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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0629; FRL-9972-66]

Fomesafen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fomesafen in or on the tuberous and corm vegetable subgroup 1C, the legume vegetable group 6, and the low growing berry subgroup 13-07G (except cranberry). Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2015-0629, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2015-0629 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information

not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2015-0629, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of October 21, 2015 (80 FR 63731) (FRL-9935-29), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5E8395) by Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W., Princeton, NJ 08540. The petition requested that 40 CFR 180.433 be amended by establishing tolerances for residues of fomesafen, 5-[2-cloro-4-(trifluoromethyl)phenoxy]-N-(methylsulfonyl)-2-

nitrobenzamide in or on the following raw agricultural commodities: vegetable, tuberous and corm, subgroup 1C at 0.025 parts per million (ppm); berry, low growing subgroup 13–07G except cranberry at 0.02 ppm; and vegetable, legume group 6 at 0.05 ppm. The petition also requested to amend 40 CFR 180.433 by removing the existing tolerances on the raw agricultural commodities bean, dry at 0.05 ppm; bean, snap, succulent at 0.05 ppm; bean Lima, succulent at 0.05 ppm; pea, succulent at 0.025 ppm; potato at 0.025 ppm; soybean at 0.05 ppm; and soybean, vegetable succulent at 0.05 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the registrant, which is available in the docket, *http://www.regulations.gov*. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fomesafen including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fomesafen follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The primary target organs of fomesafen are the liver and hematological system. Generally, hyalinization of hepatocytes provided the most sensitive toxicological endpoint (intermediate, and long term) in mammals. In the subchronic and chronic toxicity studies in rats and mice, food consumption, food efficiency, body weight, body weight gain, and histopathological changes in the liver were parameters that were most often affected. In addition, dogs, rats, and mice also showed hematological changes (e.g., decreased erythrocyte count, hemoglobin, or hematocrit). No progression of hematological effects was observed beyond 90 days. Neurotoxicity (decreased motor activity) was observed at doses above those causing liver toxicity or impacting hematological parameters. Post-implantation loss was noted in the developmental study,

but no quantitative or qualitative evidence of increased susceptibility was seen following *in utero* exposure to rats or rabbits in developmental studies or in the reproduction study. As the etiology of the post-implantation loss is unknown, it is considered to be both a maternal and fetal endpoint. Fomesafen can result in suppression of anti-SRBC IgM response; however, this immunotoxic potential was noted only at high doses.

Carcinogenicity was not observed in the rat chronic toxicity/ carcinogenicity study. Liver tumors were produced in the mouse carcinogenicity study; however, the Agency determined that fomesafen should be classified as "Not Likely to be Carcinogenic to Humans." This decision was based on the weight-of-evidence which supports activation of peroxisome proliferator-activated receptor alpha (PPARα) as the mode of action for fomesafen-induced hepatocarcinogenesis in mice. Fomesafen was not considered to be mutagenic.

Specific information on the studies received and the nature of the adverse effects caused by fomesafen as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document titled "*Fomesafen: Draft Human Health Risk Assessment for Registration Review and for the Section 3 Registration Action on Tuberous and Corm Vegetables (Crop Group 1C), Legume Vegetable (Crop Group 6) and Low Growing Berry (Except Cranberry) (Crop Group 13-07G)*" on pages 36-45 in docket ID number EPA-HQ-OPP-2015-0629.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

A summary of the toxicological endpoints for fomesafen used for human risk assessment is shown in the Table of this unit.

Table Summary of Toxicological Doses and Endpoints for Fomesafen for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety	RfD, PAD, LOC for Risk	Study and Toxicological Effects

	Factors	Assessment	
Acute dietary (Females 13-49 years of age)	No toxic effects of fomesafen attributable to a single dose and specific to females of ages 13-49 were found in the database.		
Acute dietary (General population including infants and children)	NOAEL = 100 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 1 mg/kg/day aPAD = 1 mg/kg/day	Acute neurotoxicity test in rat LOAEL = 250 mg/kg/day based on decreased motor activity (horizontal and vertical activity and time in central quadrant) in males
Chronic dietary (All populations)	NOAEL= 1 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.01 mg/kg/day cPAD = 0.01 mg/kg/day	Subchronic toxicity in the dog LOAEL = 25 mg/kg/day based on hematology (decreased hemoglobin and hematocrit concentrations and erythrocyte count and increased platelet count and prothrombin time)
Cancer (Oral, dermal, inhalation)	Classification: The Agency has classified Fomesafen as "Not Likely to be Carcinogenic to Humans"		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to fomesafen, EPA considered exposure under the petitioned-for tolerances as well as all existing fomesafen tolerances in 40 CFR 180.433. EPA assessed dietary exposures from fomesafen in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for fomesafen. In estimating acute dietary exposure, EPA used 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance level residues and 100 percent crop treated (PCT).

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used 2003-2008 food consumption data from the USDA's NHANES/WWEIA. As to residue levels in food, EPA assumed tolerance level residues and 100 PCT.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that fomesafen does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue or PCT information in the dietary assessment for fomesafen. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fomesafen in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fomesafen. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the Pesticide in Water Calculator (PWC) model (Version 1.52) the estimated drinking water concentrations (EDWCs) of fomesafen for acute exposures are estimated to be 168 parts per billion (ppb) and for chronic exposures are estimated to be 125 ppb. These modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Fomesafen is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found fomesafen to share a common mechanism of toxicity with any other substances, and fomesafen does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fomesafen does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. There is no evidence of increased susceptibility of rat fetuses to *in utero* exposure to fomesafen. Post-implantation loss was observed in the rat developmental toxicity study. However, as the etiology of the effect is unknown, it is considered to be a part of both a maternal and fetal effect. The 2-

generation reproduction study in rats did not show evidence of increased susceptibility to fomesafen. Although the developmental toxicity study in rabbits was classified as unacceptable due to mortality from bacterial infections, there was adequate information to show that there was no evidence of increased susceptibility of rabbit fetuses due to the treatment with fomesafen.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

i. The toxicology database for fomesafen is complete and sufficient for assessing potential susceptibility to infants and children. Although the developmental toxicity study in rabbits was classified unacceptable due to mortality from bacterial infections, there was no evidence of increased susceptibility of rabbit fetuses due to the treatment with fomesafen. Therefore, the lack of an acceptable developmental toxicity study in non-rodents is not considered a data gap.

ii. There is no need for a developmental neurotoxicity study or a need to retain the FQPA SF to account for the lack of such study. Decreased motor activity (horizontal and vertical activity and time in central quadrant) was observed in male rats in the acute neurotoxicity screening battery. In the subchronic neurotoxicity test, neither general systemic toxicity nor neurotoxicity was observed at the highest dose tested. All points of departure used in the risk assessment are protective of potential neurotoxicity.

iii. There is no evidence that fomesafen results in increased susceptibility in *in utero* rats in the prenatal developmental studies or in young rats in the 2-generation

reproduction study. Although the developmental toxicity study in rabbits was classified as unacceptable due to mortality from bacterial infections, there was adequate information to show that there was no evidence of increased susceptibility of rabbit fetuses due to the treatment with fomesafen.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fomesafen in drinking water. These assessments will not underestimate the exposure and risks posed by fomesafen.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to fomesafen will occupy 2.9% of the aPAD for all infants less than 1-years old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fomesafen from food and

water will utilize 70% of the cPAD for all infants less than 1 year old, the population group receiving the greatest exposure. There are no residential uses for fomesafen.

3. *Short- and Intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Both short- and intermediate-term adverse effects were identified; however, fomesafen is not registered for any use patterns that would result in either short- or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess either short- or intermediate-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for fomesafen**.**

4. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, fomesafen is not expected to pose a cancer risk to humans.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to fomesafen residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate residue analytical methods are available for the purpose of fomesafen tolerance enforcement for plant commodities. A high performance liquid chromatography method with tandem mass spectrometry detection (LC/MS/MS) method (GRM045.01A) has previously been submitted as an enforcement method. The method uses extraction procedures similar to previous methods, SPE cleanup procedures, and the final determination step by LC/MS/MS for analysis of fomesafen residues. The validated limit of quantitation (LOQ) of the method is 0.02 ppm.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established any MRLs for fomesafen.

C. Response to Comments

Two comments were received in response to the notice of filing. The first was related to a different chemical, azoxystrobin, and is therefore not relevant to this action. The second was from the Center for Biological Diversity and centered primarily around impacts on endangered and threatened species. This comment is not relevant to the Agency's evaluation of safety of the fomesafen tolerances under section 408 of the FFDCA, which requires the Agency to evaluate the potential harms to human health, not effects on the environment.

V. Conclusion

Therefore, tolerances are established for residues of fomesafen, including its metabolites and degradates, in or on the following commodities: Berry, low growing, subgroup 13-07G, except cranberry at 0.02 ppm; vegetable, legume, group 6 at 0.05 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.025 ppm. In addition, the following existing tolerances are removed as unnecessary since they are superseded by the newly established tolerances: Bean, dry at 0.05 ppm; bean, lima, succulent at 0.05 ppm; bean, snap, succulent at 0.05 ppm; pea, succulent at 0.025 ppm; potato at 0.025 ppm; soybean at 0.05 ppm; and soybean, vegetable, succulent at 0.05 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has

exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001); Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997); nor is it considered a regulatory action under Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the

distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq*.), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 25, 2018.

Michael L. Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.433, amend the table in paragraph (a) by:

i. Removing the commodities "Bean, dry"; "Bean, lima, succulent"; and "Bean, snap, succulent";

ii. Adding alphabetically the commodity "Berry, low growing, subgroup 13-07G, except cranberry";

iii. Removing the commodities "Pea, succulent"; "Potato"; "Soybean"; and "Soybean, vegetable, succulent"; and

iv. Adding alphabetically the commodities "Vegetable, legume, group 6" and "Vegetable, tuberous and corm, subgroup 1C".

The additions read as follows:

§ 180.433 Fomesafen; tolerances for residues.

(a) * * *

Commodity	Parts per million
****	***
Berry, low growing, subgroup 13-	0.02

07G, except cranberry	
****	***
Vegetable, legume, group 6	0.05
Vegetable, tuberous and corm, subgroup 1C	0.025
****	***

* * * * *

[FR Doc. 2018-02344 Filed: 2/6/2018 8:45 am; Publication Date: 2/7/2018]